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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------|--|----------------------|---------------------|------------------|
| 10/725,080 | 12/02/2003 | Mark Zoller | 54074D3 | 2713 |
| | 7590 01 <i>/24/</i> 200 [,] /ILLIAMS LLP | EXAMINER | | |
| | AL PROPERTY DEPA | LANDSMAN, ROBERT S | | |
| 1900 K STREET, N.W. SUITE 1200 | | | ART UNIT | PAPER NUMBER |
| WASHINGTO | N, DC 20006-1109 | 1647 | | |
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| SHORTENED STATUTOR | Y PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | Application No. | Applicant(s) | | | |
|---|---|--|--|--|--|--|
| Office Action Summary | | 10/725,080 | ZOLLER ET AL. | | | |
| | | Examiner | Art Unit | | | |
| | | Robert Landsman | 1647 | | | |
| Period fo | The MAILING DATE of this communication app or Reply | ears on the cover sheet with the c | orrespondence address | | | |
| WHIC - Exter after - If NC - Failu Any | ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATE in may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. In period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be time till apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | |
| Status | | | | | | |
| 1) | Responsive to communication(s) filed on 19 De | ecember 2006 | | | | |
| 2a)⊠ | | action is non-final. | | | | |
| 3)□ | · · · · · · · · · · · · · · · · · · · | | | | | |
| ٽ/ٽ | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| | Globed in accordance with the practice ander 2 | A parto quayio, 1000 O.B. 11, 40 | 0.0.210. | | | |
| Dispositi | on of Claims | | | | | |
| 4)🖂 | 4)⊠ Claim(s) <u>194-199,201-207,209 and 211-258</u> is/are pending in the application. | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6) | | | | | | |
| 7) | | | | | | |
| 8)🖂 | Claim(s) <u>194-199,201-207,209 and 211-258</u> ar | e subject to restriction and/or ele | ction requirement. | | | |
| | on Papers | | | | | |
| | The specification is objected to by the Examine | | | | | |
| | The drawing(s) filed on <u>r≥[≥1≥3</u> is/are: a) ☐ acce | | Evaminor | | | |
| ובקונטו | | | | | | |
| | Applicant may not request that any objection to the o | | • • | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| ייי י | The ball of declaration is objected to by the Ex | anniner. Note the attached Office | Action of form PTO-152. | | | |
| Priority u | inder 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 2) 🔲 Notic 3) 🔲 Inform | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other: | te | | | |

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DETAILED ACTION

1. Formal Matters

A. The Amendment filed 12/19/06 has been entered into the record.

B. Claims 194-229 were pending. Claims 200, 208 and 210 have been canceled and new claims 230-258 have been added. Therefore, claims 194-199, 201-207, 209 and 211-258 are pending and are the subject of this Office Action.

C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Specification

A. All objections to the specification have been withdrawn in view of Applicants' amendments except for the following – Though Applicants have pointed out that Figure 3C does appear in the Brief Description, the beginning of the Description must refer to Figure 3C (e.g. "Figures 3A-3C contain...")

- B. Figure 1 is objected to since it recites "rate" instead of "rat."
- C. Figure 1 is further objected to since the names of all the T1Rs are not legible. This is especially important since various claims (e.g. claim 230) refer to this Figure.

3. Claim Objections

- A. The objection to claims 220 and 221 regarding "comprised in" has been withdrawn in view of Applicants' amendments.
- B. Claim 196 is objected to since it recites "rate" instead of "rat.".
- C. Claim 217 is objected to since it recites "reporter" instead of "receptor."

4. Election by Original Presentation

A. Newly submitted claims 232-236 and 238-253 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the new claims are drawn to

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cells, extracts and lipid bilayers (class 435, subclasses 69.1 and 325) whereas the original claims are drawn to proteins (530/350).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. However, claim 236 and 238-253 WILL NOT BE WITHDRAWN FROM CONSIDERATION as being directed to a non-elected invention since it is believed these claims were written incorrectly and should likely be drawn to "An isolated heteromeric taste receptor of claim ____ expressed in a cell..." or "An isolated...expressed in a lipid bilayer..." It is noted that reciting "the cell" will have no antecedent basis.

The Examiner will wait for Applicants' response before restricting these claims. See 37 CFR 1.142(b) and MPEP § 821.03.

5. Claim Rejections - 35 USC § 112, first paragraph - scope of enablement

A. Claims 194-199, 201-207, 209 and 211-229 remain rejected and new claims 230-258 are also rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 3-4 of the Office Action mailed 9/21/06. Applicants have amended the claims to further limit the claimed genus. However, the genus of T1R1 and T1R3 receptors is still excessive with regard to claims 194, 207 and 217. These claims encompass the genus of receptors which hybridize under specific conditions to known receptors. Applicants imply in their claims that T1R1 and T1R3 receptors from 3 different species have been disclosed. However, due to the poor reproduction quality of Figure 1, which discloses the supposed receptors, the Examiner cannot identify three T1R1 and T1R3 receptors. Therefore, it appears Applicants have only provided guidance and working examples of, at most, two T1R1 receptors and two T1R3 (rat and human) receptors and nucleic acids (Figure 1). Therefore, undue experimentation would be required for the artisan to make and use the invention as claimed.

Furthermore, claims 230, 236 and 237 recite that the T1R1 protein is at least 95% identical to a T1R1. Applicants have not identified what structurally separates T1R1 from T1R2. Therefore, it would not be predictable to the artisan how to determine when they have a T1R1 receptor that is nearly identical to a T1R2. In other words, how is the artisan to know when a T1R2 receptor "becomes" a T1R1? Applicants have not identified the residues critical in differentiating a T1R1 from a T1R2.

In addition, claim 236 recites that the receptors are "derived from" the same species. Again, the breadth of the claims is excessive with regard to claiming all T1R1/T1R3 receptors which are "derived

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from" a particular animal species. Applicants have only identified one T1R2 sequence and two T1R3 sequences Derivatives would have one or more amino acid substitutions, deletions, insertions and/or additions to the claimed proteins.

The Examiner may withdraw this rejection with regard to the genus of T1R1 and T1R3 receptors if Applicants can demonstrate that these genii were well known at the time of the present invention (i.e. more than two known receptors) and that the structural similarities were sufficient enough for the artisan to identify members of these genii.

6. Claim Rejections - 35 USC § 112, first paragraph - written description

A. Claims 194-199, 201-207, 209 and 211-229 remain rejected and new claims 230-258 are also rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 4-5 of the Office Action mailed 9/21/06. Applicants have amended the claims to further limit the claimed genus. These claims encompass the genus of receptors which hybridize under specific conditions to known receptors. However, the genus of T1R1 and T1R3 receptors is still not described.

Applicants recite, or imply, in their claims that T1R1 and T1R3 receptors from 3 different species have been disclosed. However, due to the poor reproduction quality of Figure 1, which discloses the supposed receptors, the Examiner cannot identify three T1R1 and T1R3 receptors. Therefore, it appears Applicants have only adequately described at most two T1R1 and two T1R3 (rat and human) receptors and nucleic acids and not the genus of each.

Furthermore, claims 230, 236 and 237 recite that the T1R1 protein is at least 95% identical to a T1R2. Applicants have not identified what **structurally separates T1R1 from T1R2**. Therefore, it is not understood how the artisan would be able to determine when they have a T1R1 receptor that is nearly identical to a T1R2. In other words, how is the artisan to know when a T1R2 receptor "becomes" a T1R1? Applicants have not identified the residues critical in differentiating a T1R1 from a T1R2.

In addition, claim 236 recites that the receptors are "derived from" the same species. Again, genus of all T1R1/T1R3 receptors which are "derived from" a particular animal species is not well described. Applicants have only identified at most two T1R1 sequence and two T1R3 sequences. Derivatives would have one or more amino acid substitutions, deletions, insertions and/or additions to the claimed proteins.

The Examiner may withdraw this rejection with regard to the genus of T1R1 and T1R3 receptors if Applicants can demonstrate that these genii were well known at the time of the present invention (i.e.

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more than two known receptors) and that the structural similarities were sufficient enough for the artisan to identify members of these genii.

7. Claim Rejections - 35 USC § 112, first paragraph – new matter

A. Claims 194-199, 201-207, 209 and 211-258 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have added hybridization conditions into at least claims 194, 207 and 217 and state that support for these conditions can be found throughout the specification. However, upon reviewing the large specification, the Examiner was unable to find any disclosure of the exact conditions newly added to the claims.

8. Claim Rejections - 35 USC § 112, second paragraph

- A. All rejections under 35 USC 112, second paragraph, have been withdrawn in view of Applicants' amendments to the claims.
- B. Claims 232-236 and 238-251 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite "the cell" in the preamble. However, the originally elected claims are drawn to receptors. It is believed that these claims should recite "the isolated heteromeric taste receptor of claim ___ wherein the cell…"
- C. Claims 236 and 238-251 recite the limitation "the cell." There is insufficient antecedent basis for this limitation in these claims. It is believed that these claims should depend from claim 231.

9. Double Patenting

A. Claims 194-199, 201-207, 209 and 211-229 remain rejected and new claims 230-258 are also rejected for the reasons already of record on page 6 of the Office Action 9/21/06. Applicants ask that this rejection be held in abeyance until the application is allowable.

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10. Conclusion

A. No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 10 AM - 7 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Landsman Primary Examiner Art Unit 1647